CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED ADOPTION OF THE CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NON-PROFIT INSTITUTIONS

HEARING DATE: None Scheduled.

SUBJECT MATTER OF PROPOSED REGULATIONS: CIRM Grants Administration Policy for Academic and Non-Profit Institutions

SECTIONS AFFECTED: The proposed regulations adopt Chapter 5 and section 100500 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH ADOPTION:

SECTION 100500 – GRANTS ADMINISTRATION POLICY:

Purpose:

The purpose of Section 100500 is to describe the terms and conditions by which academic and non-profit institutions who are California Institute for Regenerative Medicine ("CIRM") grant recipients must abide during the term of the grant.

Subdivision (a): This subdivision describes the scope of the regulation, indicating the regulation reaches those academic and non-profit entities who are recipients of a grant, loan or guarantee from the CIRM. Health and Safety Code section 125292.10, subdivision (i), defines the term "grant" to include a "grant, loan, or guarantee." The subdivision incorporates by reference the CIRM's Grants Administration Policy for Academic and Non-Profit Institutions, which is anticipating final approval on December 7, 2006.

Subdivision (b): This subdivision identifies which provisions of the policy are being incorporated by reference. The policy contains six primary sections, identified by Roman numerals "I" through "VI." Sections "II" through "VI" are incorporated in their entirety, whereas only parts "I.B.", "I.C." and "I.E.2." are incorporated from Section "I."

Subdivision (c): This subdivision indicates when amendments to the policy (effectuated by amendment to this regulation) are effective as to grants already funded and active. In such circumstances, the new policy terms will become effective on the start date of the next budget period after the effective date of the amendment.

Subdivision (d): This subdivision indicates the term of enforcement of the policy and informs grantees that should the CIRM cease to exist the provisions of the regulation remain enforceable by the State of California.

Rationale:

Subdivision (a) is necessary to provide clarity in the scope of the policy – applicable to academic and non-profit grantees of CIRM funding. Pursuant to the definition already provided in Proposition 71, the regulation reaches all grants, loans or guarantees from the CIRM. The subdivision establishes the rule that all covered recipients are bound by the terms and conditions of the policy.

Title 1 of the California Code of Regulations, section 20, permits agencies to incorporate by reference documents under certain conditions. Subdivision (c)(1) of that regulation allows such incorporation when to do otherwise be "cumbersome, unduly expensive, or otherwise impractical" to publish the document in regulatory form. In light of the size and magnitude of the policy and given the burdens associated with translating each of the document's separate provisions into specific regulations, incorporation by reference serves the needs of both efficient use of resources, avoids the cumbersome task of rewriting an entire manual, and avoids the risk of inadvertent disagreement between the regulations and the policies being implemented.

Subdivision (b): This section clarifies the specific sections of the policy which are being incorporated by reference, as permitted by Title 1 of the California Code of Regulations, section 20, subdivision (c)(5). Because the unincorporated parts of Section "I" of the policy are informational or background material only, they are not incorporated in the regulation.

Subdivision (c): This subdivision is necessary to address what will be a common-place circumstance, wherein active grants that may span several years will become subject from time to time to amendments to the policy. Once those amendments are effective (through amendment of the policy and the regulation incorporating it), the regulation clarifies that the amended policy will become effective as to existing grants at the start of the next budget period.

Subdivision (d): The rationale for this subdivision is to ensure that grantees are aware that the terms and conditions of the grant awards survive even in the event the CIRM should no longer exist.

DOCUMENT INCORPORATED BY REFERENCE:

CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NON-PROFIT INSTITUTIONS
VERSION: DECEMBER 7, 2006

SECTION I. GENERAL INFORMATION:

Purpose:
The incorporated sections set out a key to the abbreviations used throughout the document and contain a glossary of the terms. In addition, the roles and responsibilities of grantee organization staff are described.

Section I.B. Abbreviations: The purpose is to provide a key of commonly used acronyms.

Section I.C. Glossary: The definitions contained in this section shall apply to their respective terms used in the policy. Definitions of the following terms are based on definitions from NIH Grants Policy, from December 2003: Application, Approved Budget, Authorized Organizational Official, Budget Period, Clinical Research, Equipment, For-Profit Organization, Full-Time Appointment, Grant, Grant-Supported Project or Activity, Grantee, Human Subject, Indirect Costs, Key Personnel, Notice of Grant Award, Organization, Other Support, Principal Investigator/Program Director, Prior Approval, Progress Report, Recipient and Stipend.

Rationale: To make specific the language and terminology used in formulating these regulations.

Section I.E.2. Roles and Responsibilities – Grantee Organization Staff:
Purpose: This section describes who on the grantee organization staff is an "authorized organizational official" and who is a principal investigator or program director. The section indicates the authorized official is a designated representative of the grantee whose signature of on the grant application certifies the accountability of the organization for appropriate use of funds and performance, as well as compliance with applicable state and federal laws governing the covered activity. The Principal Investigator ("PI") or Program Director ("PD") is the official charged with ensuring compliance with the financial and administrative aspects of the award. The PI must have a formal written agreement with the grantee organization identifying the official relationship between the two.

Rationale: Roles and responsibilities of grantee organization staff are commonplace and addressed in similar policies of the National Institutes of Health ("NIH") and Special Research Programs at UCOP ("SRP"). In order to ensure proper oversight of CIRM grants, appropriate individuals within grantee institutions must be identified and charged with assuming responsibility for compliance with pertinent rules.

SECTION II. GRANT APPLICATION AND REVIEW PROCESS.

Purpose:

Subpart A. Eligibility: Eligibility requirements for applicants for CIRM funding must meet the described criteria. In addition, the subpart describes the educational requirements for service as a PI or PD. Any additional requirements specific to a given grant will be contained in grant announcements.

Subpart B. Application Submission: Identifies how grant funding opportunities will be announced by the CIRM, through the use of Requests for Applications ("RFA's"). The section also indicates that a Letter of Intent may be required under specific RFA's prior to submission of a full application.

Subpart C. Legal Effect of Signed/Submitted Application: This subpart states that an authorized organizational official's signature on an application warrants that all eligibility requirements are met and that terms and conditions of an award will be followed.

Subpart D. Application Review: This section describes for applicants how applications are reviewed by the Scientific and Medical Research Funding Working Group ("SMRFWG").

Subpart E. Criteria for Review. Health and Safety Code section 125290.60, subdivision (c), requires evaluation of grant applications based on criteria established by the ICOC. The section identifies the eight standard criteria and identifies additional criteria in evaluating the entire portfolio of grant applications under review by the SMRFWG.

Subpart F. Appeals of Scientific Review: This subpart describes the process for applicants to appeal the review conducted by the SMRFWG.

Subpart G. Approval for Funding: This clarifies that it is the ICOC that makes all decisions regarding whether to fund a grant application.

Subpart H. Policy on Collection and Use of Personal Information: This section describes the CIRM's policy to respect the privacy of individuals. The section makes clear that the California Public Records Act may yet require the CIRM to disclose certain information.

Subpart I. Public Access to Public Records. This section clarifies CIRM's responsibilities for compliance with the California Public Records Act ("PRA") and describes specific provisions in Proposition 71 governing applicability of the PRA to the CIRM and the SMRFWG.

Rationale:

These subdivisions are necessary to meet statutory requirements of the CIRM and its working groups governing the retention and maintenance of records regarding CIRM-funded research, as well as to comply with the establishment and application of standards governing the criteria for evaluating grant applications. The description of the review process ensures grantees are aware of the expectations placed on them during the grant process and what can be expected of the CIRM during the evaluation of the applications.

SECTION III. PRE-AWARD AND AWARD.

Subpart A. Administrative Review.
Purpose: This aspect of the policy advises grantees of the nature and scope of administrative review of applications approved by the ICOC for funding. The reviews address the budget to ensure proposed costs are allowable and ensure all funding requirements are or can be met. Amended budgets to removed unallowable costs may be required. This section states that the ICOC may render conditional approvals of applications contingent upon grantee acceptance of a reduced project period or narrowed scope of work from that proposed in the application.

Rationale: Administrative review terms are specified in NIH policies and those of the SRP, for instance. These provisions ensure flexibility for both applicant and the ICOC in funding necessary research.

Subpart B. Liability.
Purpose: This section indicates, pursuant to Health and Safety Code section 125290.45, subdivision (a)(2), respective indemnity and liability rules applicable to CIRM grantees. The section identifies minimum insurance requirements to ensure compliance with the Health and Safety Code.

Rationale: CIRM does not assume responsibility for the conduct of activities that the grant supports or for the acts of the grantee. Accordingly, and as required by Proposition 71, grantees are required to assume liability responsibilities as outlined in this subpart.

Subpart C. Public Policy Requirements.
Purpose: This subpart identifies public policies governing certain activities upon which CIRM funding is contingent. This subpart requires conduct of research be compliant with existing federal and state requirements governing research misconduct, conflicts of interest, use of human stem cell lines, use of human fetal tissue, research involving human subjects, animal subjects, use of biohazardous materials, the sharing of intellectual property and the Proposition 71-mandated preference for California suppliers.

Rationale: These provisions are necessary to ensure adequate compliance with federal and state laws governing certain types of research. As part of its oversight function, the CIRM must identify those areas in which grantees are expected to give assurance of compliance so that CIRM is assured that funded research follows applicable rules.

Research misconduct and possible administrative remedies for misconduct are analogous to policies followed by the NIH, the American Cancer Society ("ACS"), Florida Department of Health and the Susan B. Komen Breast Cancer Foundation. Existing federal policy as embodied in Title 42, Code of Federal Regulations, Part 93, contain similar standards for such policies.

Requirements for research involving human subjects are based on Title 45, Code of Federal Regulations part 46, and policies of the NIH, the American Heart Association ("AHA"), the ACS and Department of Health and Human Services ("DHHS").

The just-in-time policy provisions allow for deferral of certain required information after approval of funding but before issuance of a Notice of Grant Award. These provisions are similar to those already in existence at the NIH and are familiar to institutions that accept federal funding for research.

SECTION IV. AWARD ACCEPTANCE.

Purpose:

This section states that an award is accepted when an NGA (Notice of Grant Award) is signed by the grantee and received by the CIRM. This section establishes the agreement by the grantee to abide by the terms and conditions of the policy. The section states that the authorized organizational official must sign and return the NGA within 30 days to accept the award. Finally, this section advises that the grants policy, as incorporated by this regulation, is subject to amendment from time to time and states the amendments become applicable to the grantee on the start of the next budget period.

Rationale:

This section is necessary to set forth the procedures for accepting a grant award and indicating the point at which an applicant becomes bound by the terms of this policy. The provisions regarding amendment of the policy are necessary to apprise grantees of the timing for application of amendments to the grants administration policy.

SECTION V. PAYMENT AND USE OF FUNDS.

The purpose of this section is to describe the procedures that will guide how and when payments of grants will be made and the rules applicable in the expenditure by grantees of those funds. CIRM funds shall only be used for expenditures necessary to carry out the approved project and activities. The section identifies specific allowable and unallowable costs that can be charged by grantees to the grant funds.

The section also describes the prohibition against budgetary overlap and prohibits the commingling of grant funds with an organization's other fund sources.

This section also describes the circumstances under which a CIRM grantee must seek prior approval from CIRM for departure from project activities described in the approved application. Prior approval is required for changes in scope of the research, for the carrying forward of funds from one grant year to the next, extensions of the project completion date, rebudgeting of funds from one section of the approved budget to another, the transfer of awards when the PI transfers to a new organization, the change in status of a PI and the procedures for submitting prior approval requests.

This section requires grantees to have property management systems for equipment and sets forth the circumstances when title to CIRM funded equipment vests in the grantee organization or the CIRM.

This section further provides that the grantee is responsible for keeping appropriate records documenting compliance with the terms and conditions of the award and providing for access by the CIRM other agencies for audit purposes.

This section states the prohibition against intentional deception or misrepresentation and requires grantees to report cases of fraud, waste or abuse under a CIRM grant. This section defines what constitutes fraud and abuse, as well.

Subpart H details the financial and programmatic reporting requirements. Grantees must report financial and scientific progress to CIRM on an annual basis. The annual programmatic report is due 60 days prior to each anniversary of the award start date indicated in the NGA. The subsequent budget period's funding will not be awarded until this report has been received, reviewed, and approved by the CIRM. In addition, the grantee must submit an annual financial report within 90 days after each anniversary of the award start date. Failure to provide reports may lead to a cessation of funding.

This section also addresses the procedures and expectations for close-out of a grant after the project period end date. Grantees remain obligated to return funds due as a result of refunds, corrections or other transactions.

Subpart J identifies the range of consequences for failure of compliance.

Rationale:

The requested information for reporting is required for effective grant management by the CIRM and for meeting specific reporting requirements of the California State Legislature. The CIRM is also responsible for disseminating the outcomes of funded research to interested constituencies, as well as to the general public.

Cost allocation formulae are necessary to ensure grantees and the public are aware of costs that are allowable and that can be assessed against the grant funds, ensuring proper expenditure of taxpayer-funded research. Prior approval requirements, which are similar to those of the NIH, AHA, SRP and JDRF, ensure that flexibility in the research process is balanced with proper oversight. Similarly, equipment management provisions, similar

to those of the NIH, AHA, SRP, and ACS, ensure that grantees are aware of the consequences of expenditures for equipment and are able to plan accordingly.

SECTION VI. SPECIAL POLICIES FOR TRAINING GRANTS.

Purpose:

This section supplements the policies described in the first five sections and provides additional or different requirements that apply specifically to CIRM-funded training grants.

Subpart A identifies the criteria for review of training grant applications. These are criteria established by the ICOC and upon which all training grant applications will be evaluated and compared.

Subpart B describes the requirements for appointment of trainees, their oversight by eligible faculty mentors, the degree requirements and the training period requirements. The purpose is to ensure that trainees are given the optimal environment for success and maximum reward for the investment of the training funds.

Subpart C describes allowable costs and activities that may be assessed against the training grants that are unique to training grants. Stipend levels are described and capped based on the level and experience of a given trainee. This section also describes the tuition and fees that will be reimbursed, health insurance that will be covered, trainee related research and travel reimbursements, and allowable requests for funds for administrative costs.

As with the main grants administration policy, Subpart D describes the specific circumstances under which prior approval by the CIRM is required for post award changes. Prior approval is required for rebudgeting funds out of the stipend category, for training periods for a clinical trainee for period less than 12 consecutive months, rebudgeting among administration funds, the carrying forward of funds that exceed 25 percent of the annual project costs for the expiring year, extensions of the scheduled end date, a change in the program director and a change in a sponsor or mentor.

Subpart E details reporting requirements for financial and programmatic progress on an annual basis. The programmatic report is due 60 days prior to each anniversary of the award start date indicated in the NGA. The subsequent year's funding will not be awarded until this report has been received, reviewed, and approved by the CIRM. In addition, the program director must submit an annual financial report within 90 days after each anniversary of the award start date.

This grants administration policy statement serves as the interim terms and conditions of training grant awards issued by the California Institute for Regenerative Medicine (CIRM). In addition, it provides guidance to recipients on their responsibilities as CIRM grantees. Program directors and organizational officials with grants management

responsibilities are urged to read this document carefully and to refer to relevant sections for answers to questions that arise concerning the administration of CIRM training grants. The CIRM is developing a comprehensive grants administration policy statement that will describe the terms and conditions (including public policy requirements) that apply to all CIRM grants. The comprehensive grants administration policy statement will incorporate the policies described in this document for the CIRM training grants. Grantees should be aware that certain public policies that apply to intellectual property rights and the use of human embryonic stem cells are not yet finalized. Grantees will be expected to comply for the entire period of the grant with the relevant provisions set forth in the comprehensive grants administration policy statement as approved by the ICOC and with any regulations adopted by the ICOC. Any new or revised CIRM policies, including regulations, that are described in the comprehensive grants administration policy statement or that are adopted by the ICOC will be applied retroactively to all awarded CIRM grants. CIRM will notify training grant program directors and grantee organizations when the comprehensive grants administration policy statement and applicable regulations are available and in effect.
The CIRM Training Program will provide support to California public colleges, universities, and non-profit biomedical research institutions to develop or enhance training in stem cell biology. The purpose of the CIRM Training Program is to ensure that highly trained scientists and clinicians are available in adequate numbers and in the appropriate research areas to carry out the goals set forth by the California Stem Cell Research and Cures Act.

Rationale:

The requested information for reporting is required for effective grant management by the CIRM and for meeting specific reporting requirements of the California State Legislature. The CIRM is also responsible for disseminating the outcomes of funded research to interested constituencies, as well as to the general public.